

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION**

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL No. 2327
THIS DOCUMENT RELATES TO: ETHICON WAVE 1 CASES LISTED IN EXHIBIT A	JOSEPH R. GOODWIN U.S. DISTRICT JUDGE

**PLAINTIFFS' MEMORANDUM OF LAW IN SUPPORT OF THEIR *DAUBERT*
MOTION TO EXCLUDE, OR IN THE ALTERNATIVE, TO LIMIT THE OPINIONS
AND TESTIMONY OF ROGER MCLENDON, M.D.**

Plaintiffs in actions listed on Exhibit A, pursuant to Federal Rules of Evidence 702, 403, and 104, as well as the U.S. Supreme Court decision in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993), hereby respectfully move this Court to exclude or limit certain opinions and testimony offered by the Defendants' expert Roger McLendon, M.D.

INTRODUCTION

Dr. McLendon is board certified in the specialties of Anatomic Pathology and Neuropathology. *See* Exhibit B, Expert Report of Dr. McLendon at p. 1. Yet despite these certifications, Dr. McLendon has performed no research on transvaginal mesh and how it reacts in the human body, has performed no research on the cause of pain in women implanted with these pelvic mesh products, and has not observed any transvaginal mesh specimens; the issues that are at the very heart of this case and his proposed testimony. *See* Exhibit C, 9/29/15 Deposition of Dr. McLendon at 9:5-22, 10:9-15, 58:1-5, 116:2-6. According to Dr. McLendon himself, when it comes to implantable medical devices, "I don't know the science. I don't know the medicine." *Id.* at 79:12-81:4. Dr. McLendon's entire report can be characterized as a cross-

examination of plaintiff's expert, Dr. Iakovlev. *See* Ex. B. He seeks to testify to a myriad of reasons why Dr. Iakovlev is wrong, but cannot offer any reliable explanation as to why this is so, or any affirmative opinions to the contrary. Dr. McLendon is simply not qualified to form opinions related to Dr. Iakovlev's findings or the ability of transvaginal mesh to cause pain; further, he has no reliable, scientific basis to do so.

Dr. McLendon's experience in the field of Anatomic Pathology and Neuropathology does not render all of his opinions admissible. Even with certain qualifications, an expert must use a reliable, scientific methodology when forming their opinions.¹ Yet Dr. McLendon fails to use any true methodology at all in this case. The admissibility of Dr. McLendon's unreliable or unfounded opinions presents a serious risk of confusing the issues and misleading the jury in this case.² Accordingly, Dr. McLendon should be prevented from offering testimony or opinions that exceed those permitted under *Daubert* and its progeny.

LEGAL STANDARD

For the sake of brevity and because the Court is fully aware of the legal standards governing the admissibility of expert testimony in the Fourth Circuit, Plaintiffs will not set forth a detailed discussion of the legal standard. It is known and understood that the admissibility of expert testimony is governed by the Federal Rules of Evidence, including but not limited to

¹ *See Phelan v. Synthes*, 35 Fed. Appx. 102, 105(4th Cir. 2002) (the reasoning or methodology underlying testimony must be scientifically valid and able to be properly applied to the facts in issue.); *Cisson v. C.R. Bard, Inc.*, MDL No. 2187, 2013 U.S. Dist. LEXIS 78061, *42-43 (S.D.W.V. 2013) (“[j]ust because an expert may be ‘qualified . . . by knowledge, skill, experience, training or education’ does not necessarily mean that the opinion that the expert offers is ‘the product of reliable principles and methods’ or that the expert ‘has reliably applied the principles and methods to the facts of this case.’”)

² *See Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999)(“[T]he court must recognize that due to the difficulty of evaluating their testimony, expert witnesses have the potential to ‘be both powerful and quite misleading.’”(citing *Daubert*, 509 U.S. at 596).

Rules 702, 403 and 104.³ The trial judge acts as a gatekeeper for scientific, technical and other specialized knowledge.⁴

ARGUMENT

I. Dr. McLendon is not qualified to offer any opinions about Dr. Iakovlev's methodology and findings, nor is he qualified to opine on whether transvaginal mesh can cause pain in patients.

The primary focus of Dr. McLendon's expert report is to criticize Dr. Iakovlev's methodology and findings relating to transvaginal mesh and its ability to cause pain, including his analysis of various images of pathology slides. The pertinent question here is not whether or not Dr. McLendon is right or wrong, and Plaintiffs do not need to challenge these opinions based on their accuracy.⁵ To put it simply, Dr. McLendon has absolutely no experience that qualifies him to offer such a critique of Dr. Iakovlev. Indeed, he has never even looked at a pathological specimen involving polypropylene or performed any research whatsoever on how a mesh implant may respond in the human body.⁶ Dr. McLendon clarified his shortcomings at this deposition, testifying that:

- He has performed no research himself on transvaginal mesh implants and how they react in the human body. Exhibit C, 9/29/15 Deposition of Dr. McLendon at 58:1-5.
- He has never looked at a transvaginal mesh specimen. *Id.* at 9:5-22, 10:9-15.
- He is unsure if he has ever looked a specimen involving polypropylene. *Id.* at 11:2-10.
- He never looked at a TVT explant in his life prior to his deposition. *Id.* at 83:9-14.

³ See *Bryte v. Am. Household, Inc.*, 429 F.3d 469, 476 (4th Cir. 2005)(federal law governs admissibility of expert testimony).

⁴ See *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 587 (1993); *Kumho Tire Co., Ltd., v. Carmichael*, 526 U.S. 137, 141 (1999).

⁵ See *Westberry*, 178 F.3d at 261(the focus is on the principles and methodology, not the conclusions reached. Further, the court need not determine if expert testimony is irrefutable or necessarily correct.)

⁶ Notably, this is in stark contrast to the experience of Dr. Iakovlev, who has devoted substantial practice to review and analysis of mesh pathology.

- He has never looked at any abdominal mesh implants. *Id.* at 25:22-26:25.
- He does not develop prostheses or do any studies on the implantation of prostheses. He does not know the science or medicine related to this. *Id.* at 79:12-81:4.

Even more, Dr. McLendon claims that Dr. Iakovlev's opinions are flawed largely because, in his opinion, he ignored certain studies that would be incorporated in literature on chronic persistent pain. Yet when asked about these studies, Dr. McLendon was unable to provide specific answers because according to him, chronic persistent pain is not his area of expertise. *Id.* at 112:14-113:14, 114:2-4. If Dr. McLendon is admittedly not qualified to discuss these topics, he certainly is not qualified to criticize Dr. Iakovlev's studies and findings in this field. Dr. McLendon is wholly unqualified to offer opinions on Dr. Iakovlev's methods and findings, as well as any opinions related to pain causation and transvaginal mesh. His testimony should therefore be excluded in its entirety.

II. Dr. McLendon does not rely on any scientific basis to form his opinions in this case, including his criticisms of Dr. Iakovlev and any opinion related to the causal link between transvaginal mesh and pain.

Even if this Court finds that Dr. McLendon is qualified to render these opinions, he must still base his opinions on a reliable, scientific method.⁷ It is clear that Dr. McLendon fails to use any scientific method here that this Court can assess, much less a reliable one. First and foremost, Dr. McLendon has not performed any research on how transvaginal mesh implants react in the human body; he therefore has no foundation at all for critiquing Dr. Iakovlev's findings on this topic. Dr. McLendon has no idea how many studies Dr. Iakovlev has performed or how many are published. Ex. C, 82:4-13. He acknowledges that it is possible for a woman

⁷ *Tyree v. Boston Sci. Corp.*, 54 F. Supp. 3d 501, 526, 2014 U.S. Dist. LEXIS 155138, *34 (S.D. W. Va. 2014); *See also Wise v. C. R. Bard, Inc.*, 2015 U.S. Dist. LEXIS 14869, *39 (S.D. W. Va. Feb. 7, 2015) (Relevance under *Daubert* depends on whether "a valid scientific connection" exists between the expert's testimony and the facts or issues of the case.).

with mesh to experience a pain syndrome, and that there is a correlation between mesh implants and pain, but he is unable to provide any information about potential causes of such pain. *Id.* at 20:1-5, 30:4-19, 34:14-16, 114:25-115:5.

Dr. McLendon has not performed any studies on what causes a chronic post-operative pain syndrome. *Id.* at 35:5-12. He has no active research program to determine the cause of pain in women with a mesh implant and has no plan to do so at this time. *Id.* at 116:2-6. Further, Dr. McLendon is unable to provide any information about potential sources of mesh related pain. For example, he believes it is “unknowable” if nerves that grow in or around scar tissue that surrounds a properly placed mesh can cause pain long term. *Id.* at 23:23-24:1. He is also unsure if scar tissue can stimulate nerve receptors. *Id.* at 75:23-76:9, 77:14-22.

Having performed no independent research on the transvaginal mesh and potential causes of pain, Dr. McLendon somehow seeks to testify that Dr. Iakovlev is incorrect in his methods and findings. Even more, he seeks to do so despite the fact that he cannot provide any reasoning or any information contrary to Dr. Iakovlev’s opinions. This type of “no it’s not” ipse dixit testimony is not helpful to the jury—because it provides no scientific basis upon which the jury could rely.⁸ Neither *Daubert* nor the Federal Rules of Evidence require the admission of opinion evidence that is merely *ipse dixit* of the expert, and a court may conclude that there is too large of an analytical gap between the data and the opinion proffered.⁹ That is precisely the case here. Dr. McLendon’s opinions should therefore be excluded.

⁸ *Ipse dixit* is defined as “[h]e himself said it; a bare, assertion resting on the authority of an individual.” See Black’s Law Dictionary 828 (6th ed. 1990); see also *Sadow-Pajewski v. Busch Entertainment Corp.*, 55 F. Supp. 2d 422, 427 (E.D.Va. 1999).

⁹ *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997).

III. Dr. McLendon's testimony serves no other purpose but to criticize Dr. Iakovlev, and should therefore be excluded.

As outlined in the previous section, Dr. McLendon's sole purpose in this case is to offer a list of reasons why he believes that Dr. Iakovlev's methods and findings are wrong. Yet his testimony shows that he is entirely unable to provide any affirmative opinions of his own on these topics. His inability to do so clearly illustrates his lack of qualifications in the realm of transvaginal mesh pathology and chronic pain, and this improper testimony is nothing more than a baseless attack on Dr. Iakovlev. This testimony not only is unhelpful to the jury, but will almost certainly hinder the jury's understanding of the issues in this case. Accordingly, Dr. McLendon's testimony should be excluded.

CONCLUSION

Ethicon, as the proponent of the expert testimony, bears the substantial burden of establishing that Dr. McLendon is sufficiently qualified and that the proposed testimony satisfies the applicable evidentiary standards for the admission of expert testimony. Considering the lack of experience, knowledge, and reliability inherent in Dr. McLendon's opinions, Ethicon cannot carry this burden and Dr. McLendon's testimony should be excluded in its entirety.

Dated: April 21, 2016

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that I filed the foregoing document on April 21, 2016, using the Court's CM-ECF filing system, thereby sending notice of the filing to all counsel of record in this matter.

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